



IFW

PATENT  
ATTORNEY DOCKET NO.: 061537-0036

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Juan Armendariz BORUNDA et al. Confirmation No.: 4513

Application No.: 10/724,292

Group Art Unit: 1632

Filed: December 1, 2003

Examiner: To Be Assigned

For: RECOMBINANT ADENOVIRAL  
VECTORS AND THEIR  
UTILIZATION IN THE  
TREATMENT OF VARIOUS TYPES  
OF HEPATIC, RENAL AND  
PULMONARY FIBROSIS AND  
HYPERTROPHIC SCARS

Attorney Docket No.: 061537-0036

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir:

Pursuant to Applicants' duty of disclosure under 37 C.F.R. § 1.97 and 1.98, enclosed is a Form PTO-1449 which lists thirty-nine (39) references. The references cited on the PTO-1449 were cited in the Information Disclosure Statement being filed today in the parent application, U.S. Application No. 10/098,359; therefore, copies of the documents are not enclosed. However, if the Examiner requests a copy, they will be forwarded.

It is respectfully requested that these references be made of record in this application by the Examiner's completion and return of the Form PTO-1449.

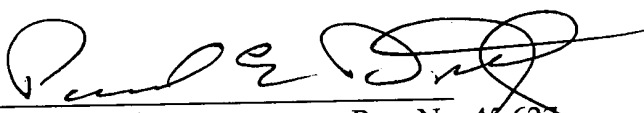
This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b); before the mailing of the first Office action on the merits in the application. No fee is believed to be due for this submission. If the U.S. Patent and Trademark Office deems a fee is due, please charge this fee and any other required fees to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310.

Respectfully submitted,

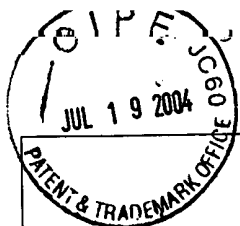
**MORGAN, LEWIS & BOCKIUS LLP**

Dated: July 19, 2004

By: \_\_\_\_\_

  
Paul E. Dietze                      Reg. No. 45,627

**CUSTOMER NO. 09629**  
**MORGAN, LEWIS & BOCKIUS LLP**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Telephone: (202) 739-3000  
Facsimile: (202) 739-3001

**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.

061537-0036

APPLICATION NO

10/724,292

APPLICANT

Juan Armendariz BORUNDA et al.

FILING DATE

December 1, 2003

GROUP

1632

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	5,166,320	11/24/1992	Wu et al.	530	395	
	A02	5,240,846	8/31/1993	Collins et al.	435	240.1	
	A03	5,521,291	5/28/1996	Curiel et al.	530	391.7	
	A04	5,547,932	8/20/1996	Curiel et al.	435	65	
	A05	5,559,099	9/24/1996	Wickham et al.	514	44	
	A06	5,585,362	12/17/1996	Wilson et al.	514	44	
	A07	5,670,488	9/23/1997	Gregory et al.	514	44	
	A08	5,712,136	1/27/1998	Wickham et al.	435	172.3	
	A09	5,756,086	5/26/1998	McClelland et al.	424	93.2	
	A10	5,770,442	6/23/1998	Wickham et al.	435	320.1	
	A11	5,827,703	10/27/1998	Debs et al.	435	172.3	
	A12	5,846,782	12/8/1998	Wickham et al.	435	697	
	A13	5,856,152	1/5/1999	Wilson et al.	435	172.3	
	A14	5,872,154	2/16/1999	Wilson et al.	514	885	
	A15	5,885,808	3/23/1999	Spooner et al.	435	172.3	
	A16	5,895,759	4/20/1999	Strauss et al.	435	320.1	
	A17	5,910,487	6/8/1999	Yew et al.	514	44	

**OTHER REFERENCES** (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	P. P. Anthony, K. G. Hishack, N. C. Nayak, H. E. Poulsen, P. J. Scheuer, L. H. Sobin; "The Morphology of Cirrhosis: Definition, Nomenclature and Classification", <u>Bulletin of the World Health Organization</u> ; 1977; 55:521-540
C02	J. Armendariz-Borunda and M. Rojkind; "A Simple Quantitative Method for Collagen Typing in Tissue Samples: Its Application to Human Liver with Schistosomiasis"; <u>Collagen Rel. Res.</u> 1984, Vol. 4, 35-47
C03	J. Armendariz-Borunda, K. Katayama and J. M. Seyer; "Transcriptional Mechanisms of Type I Collagen Gene Expression are Differentially Regulated by Interleukin-1 $\beta$ , Tumor Necrosis Factor $\alpha$ , and Transforming Growth Factor $\beta$ in Ito Cells"; <u>J. Biol. Chem.</u> 267:14316-14321; 1992

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

ATTY DOCKET NO.

061537-0036

APPLICATION NO

10/724,292

APPLICANT

Juan Armendariz BORUNDA et al.

FILING DATE

December 1, 2003

GROUP

1632

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

C04	J. Armendariz-Borunda, H. Katai, C. M. Jones, J. M. Seyer, A. H. Kang, and R. Raghov; "Transforming Growth Factor $\beta$ Gene Expression is Transiently Enhanced at a Critical Stage during Liver Regeneration Following $\text{CCl}_4$ Treatment"; <u>Laboratory Investigation</u> ; 69:283-294, 1993
C05	J. Armendariz-Borunda, C. Simkevich, N. Roy, R. Raghov, A. H. Kang and J. M. Seyer, "Activation of Ito Cells Involves Regulation of AP-1 Collagen Gene Expression"; <u>Biochemical Journal</u> 304:817-824, 1994
C06	C. Chen and H. Okayama; "Calcium Phosphate-Mediated Gene Transfer: a Highly Efficient Transfection System for Stably Transforming Cells with Plasmidic DNA"; <u>Biotechniques</u> 1988, 6:632-638
C07	J.T. Douglas and D. T. Curiel, "Adenoviruses as Vectors for Gene Therapy", <u>Science and Medicine</u> , March/April 1997, 44-53
C08	R. Dumaswala, D. Berkowitz and J. E. Heubi, "Adaptive Response of the Enterohepatic Circulation of Bile Acids to Extrahepatic Cholestiasis", <u>Hepatology</u> 1996, Vol. 23, No. 3: 623-629
C09	Scott L. Friedman, "The Cellular Basis of Hepatic Fibrosis: Mechanisms and Treatment Strategies", <u>The New England Journal of Medicine</u> 1993, Vol. 328, No. 25:1828-1835
C10	F.L. Graham and A. J. Van Der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA", <u>Virology</u> 1973, 52:456-467
C11	Tong-Chuan He, Shibin Zhou, Luis T. Da Costa, Kian Yu, Kenneth W. Kinzler and Bert Vogelstein, "A Simplified System for Generating Recombinant Adenoviruses", <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 95: 2509-2514, March 1998
C12	S. Lee, C. Girod, A. Draillon, A. Hadengue, and D. Lebec, "Hemodynamic Characterization of Chronic Bile Duct-Ligated Rats: Effect of Pentobarbital Sodium", <u>AM Journal Fisiol.</u> 1986; 251:176-180
C13	Marie-Jeanne T. F. D. Vrancken Peeters, A. Lieber, J. Perkins, and M. A. Kay; "Methods for Multiple Portal Vein Infusion in Mice: Quantitation of Adenovirus-Mediated Hepatic Gene Transfer"; <u>BioTechniques</u> February 1996; 20:278-285
C14	D. Martinez-Fong, J. E. Mullersman, A. F. Purchio, J. Armendariz-Borunda, and A. Martinez-Hernandez, "Nonenzymatic Glycosylation of Poly-L-lysine: A New Tool for Targeted Gene Delivery", <u>Hepatology</u> , Vol. 20, No. 6: 1602-1608
C15	F. Mion, A. Geloën, E. Agosto and Y. Minaire, "Carbon Tetrachloride Induced Cirrhosis in Rats: Influence of the Acute Effects of the Toxin on Glucose Metabolism", <u>Hepatology</u> 1996, Vol. 23, No. 2:582-587
C16	S. Nakano, J. Haratake, and H. Hashimoto, "Alteration in Bile Ducts and Peribiliary Microcirculation in Rats After Common Bile Duct Ligation"; <u>Hepatology</u> , 1995, Vol. 21, No. 5, 1380-1386
C17	J. L. Poo, A. Estanes, J. Pedraza-Chaverri, C. Cruz, C. Perez, A. Huberman and M. Uribe; "Cronologia de Hipertension Portal, Disminucion de Excrecion de sodio y activacion del sistema renina-angiotensina en cirrosis biliar experimental", <u>Rev., Invest Clin.</u> , 49:15-23, 1997
C18	A. Rojas-Martinez, P. R. Wyde, C. A. Montgomery, S. H. Chen, S. L. C. Woo, and E. Auilar-Cordova; "Distribution, Persistency, Toxicity and Lack of Replication of an E1A-Deficient Adenoviral Vector after Intracardiac Delivery in the Cotton Rat"; <u>Cancer Gene Ther.</u> , Vol. 5, 1998, pp. 365-370

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)		ATTY DOCKET NO. 061537-0036	APPLICATION NO 10/724,292
		APPLICANT Juan Armendariz BORUNDA et al.	
		FILING DATE December 1, 2003	GROUP 1632
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	C19	S. Shimohama, M. B. Rosenberg, A. M. Fagan, J. A. Wolff, M. P. Short, X. O. Breakefield, T. Friedmann, and F. H. Gage, "Grafting Genetically Modified Cells into the Rat Brain: Characteristics of <i>E. Coli</i> $\beta$ -Galactosidase as a Reporter Gene"; <i>Molecular Brain Res.</i> 5:271-278; 1989	
	C20	D. J. Weiss, D. Liggitt and J. G. Clark, " <i>In Situ</i> Histochemical Detection of $\beta$ -Galactosidase Activity in Lung: Assessment of X-Gal Reagent in Distinguished <i>lacZ</i> Gene Expression and Endogenous $\beta$ -Galactosidase Activity", <i>Human Gene Therapy</i> , September 1, 1997; 8:1545-1554	
	C21	M. A. Zern and T. F. Kresina, "Hepatic Drug Delivery and Gene Therapy", <i>Hepatology</i> , 1997, Vol. 25, No. 2, 484-491	
	C22	G. Zhu, A. G. Nicolson, X. Zheng, T. B. Strom and V. P. Sukhatme; "Adenovirus-Mediated $\beta$ -Galactosidase Gene Delivery to the Liver Leads to Protein Deposition in Kidney Glomeruli"; <i>Kidney International</i> ; 1997, Vol. 52, 992-999	
	C23		
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			